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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,493	09/28/2001	Joseph Luber	MCP-0274	5286

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,493	LUBER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 08/31/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. 6,099,859, or Smith et al. 6,194,000, or Harbit 3,108,046, in view of Remon (WO 01/21155 A1).

Cheng teaches a controlled release oral tablet comprising from 75-95% drug and up to about 40% waxes (see column 3, lines 34-49; and column 5, lines 30-36). The tablet provides both, immediate release and controlled release (see column 5, lines 22-26). The tablet further comprises fatty acid, surfactant (flow aid), and chelating agent (column 3, lines 51-60), and can further be coated with a semi-permeable membrane comprises cellulose derivatives polymer (see column 4, lines 11-44). Cheng also discloses the tablet is prepared by compression (see column 6, lines 35-41).

Smith teaches an analgesic composition comprising immediate and controlled release forms (see abstract). The immediate release comprises up to 90% of the analgesic agent, polyethylene glycol, waxes, and other carriers (column 2, lines 39-50; and column 3, lines 29-51). The dosage form provides from about 1-5000 mg/day of

the analgesic agent (ID). The composition is in for oral administration in tablet or capsule or granule form (column 2, lines 55-67). Suitable coating to provide sustained release comprises cellulose derivatives polymer (column 4, lines 26-45).

Harbit teaches a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

It is noted that the references do not explicitly teach wax in powder form.

Remon discloses a rapidly disintegrating tablet comprising an active agent and wax particles (page 10, lines 14-18; page 19, lines 10-21). The wax is a microcrystalline wax or a natural wax (page 11, line 7 through page 15, line 8). The composition further contains disintegrants, swellable materials as well as other fillers (page 15, line 9 - page 18, line 6). The average size of the wax particles is from 0.5 to 2.0 mm (page 18, lines 7-18). The actives are chosen from a wide variety of known pharmaceutical agents (page 19, line 22 - page 20, line 18). The composition also includes a film coating (page 21, line 4 - page 22, line 8). The tablets are produced by compression (page 23, lines 3-9). The tablets are rapid disintegration tablets (page 24, line 16 - page 25, line 1). Remon does not refer to the wax particles as powder. However, the Examiner refers to the Hawley's Condensed Chemical Dictionary, 12 Edition, 1993, pp. 960-61 as a reference of interest. The dictionary defines a powder as any solid, dry material of extremely small particle size. Thus, it would have been obvious for one of ordinary skill in the art to modify the composition of Cheng, or Smith

using the wax in view of the teaching of Remon, because Remon teaches tablet composition suitable in pharmaceutical art.

Regarding claim 16, Remon does not expressly teach the same particle size for the wax particles. However, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary particles sizes in tablet formulations. It is the position of the Examiner that this is limitation that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the ad at the time the invention was made.

Response to Arguments

Applicant's arguments filed 08/31/05 have been fully considered but they are not persuasive.

The 102(b) and (e) rejections have been withdrawn in view of applicants' arguments filed 08/31/05 (pages 6-16).

The 103(a) rejection over Robinson in view of Remon has been withdrawn in view of applicant's statement in page 19 of Remarks filed 08/31/05.

Applicant argues that it is not seen where Remon discloses wax particles. Further, the definition of the term "powder" is not needed to understand the claimed invention, because it is not seen where any of the primary references cite the term "powder" in conjunction with the term "wax", and because if Remon were to have

intended use powder wax, Remon would have used the term. In response to applicant's argument, the very fact Remon states "microcrystalline" hydrocarbon wax, implies that it is in a particle (powder) form. As of the publication date of Remon, microcrystalline hydrocarbon wax has been known at that time to have particle size in the range of about 2.5 to about 500 nanometers (see Kornhaber et al. at column 12, lines 45-49). Further evident by the teaching of Mueller et al. at column 2, lines 58-63, that microcrystalline wax having particle size of about 1 μm to about 300 μm. These references are prompted by applicant's remarks, and therefore, it is not a new ground of rejection. Accordingly, the teaching of particle wax in Remon is implicit.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kornhaber et al., and Mueller et al. are cited as of interest for the teachings of microcrystalline wax in particle form.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
AU 1615